

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

**THE BOARD OF REGENTS OF THE
UNIVERSITY OF TEXAS SYSTEM**

Plaintiff,

vs.

**ALNYLAM PHARMACEUTICALS INC. AND
ALNYLAM U.S., INC.**

Defendants.

Civil Action No. 1:24-cv-1524

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff the Board of Regents of The University of Texas System (“The University of Texas System,” “MD Anderson,” or “Plaintiff”) files this Complaint against Alnylam Pharmaceuticals Inc. and Alnylam U.S., Inc. (collectively, “Alnylam” or “Defendant”) for infringement of the U.S. Patent No. 8,895,717 (“717 Patent”) (Exhibit 1). *See* Exhibit 2 (describing infringement).

THE NATURE OF THE ACTION

1. The University of Texas M. D. Anderson Cancer Center is a member institution of The University of Texas System and is one of the world’s premier cancer hospitals and cancer research institutions. MD Anderson’s clinical physicians and research scientists are at the forefront of medical innovation, developing lifesaving treatments for cancer and other devastating diseases and illnesses. This case is about a team of MD Anderson research scientists and their novel invention, how their invention has saved lives, and how Alnylam used the invention, without MD Anderson’s permission, to generate more than a billion dollars for Alnylam’s shareholders.

Alnylam intentionally cut MD Anderson out from sharing in any of its profits even though their use of MD Anderson's life-saving invention is what made it possible for Alnylam to generate such profits for its shareholders.

2. In the mid-2000s, two MD Anderson cancer research scientists, Drs. Anil K. Sood and Gabriel Lopez-Berestein (in collaboration with two post-graduate fellows, Drs. Charles Landen and Arturo Chavez-Reyes) developed a novel invention that effectively delivers "small interfering RNA" ("siRNA") into human cells. By delivering different types of siRNA into human cells, Drs. Sood and Lopez-Berestein's invention can be used to treat a variety of serious medical conditions, including, but not limited to, cancer and other genetic disorders. Drs. Sood and Lopez-Berestein disclosed and claimed their invention in a patent application that was filed April 15, 2005. The patent application ultimately issued as the '717 Patent.

3. In 2007, Alnylam expressed interest in Drs. Sood's and Lopez-Berestein's research and the novel technology disclosed under the then-pending patent application that became the '717 Patent. At Alnylam's request, the two research scientists presented their research to Alnylam, including the invention as claimed in the '717 Patent, under a non-disclosure agreement. Alnylam and MD Anderson then entered into an evaluation agreement to facilitate Alnylam's evaluation of MD Anderson's invention. After several years of evaluation and substantial discussions with Drs. Sood and Lopez-Berestein, Alnylam informed MD Anderson that it did not need a license to MD Anderson's invention. As it turns out, Alnylam was nonetheless planning to use MD Anderson's invention in a new—and, as it turned out, highly profitable—product.

4. At the time of its work with Drs. Sood and Lopez-Berestein, Alnylam had no commercial products and had been operating at a loss for many years. Those losses continued to mount and, by 2017, the company had accumulated a deficit of more than \$1.6 billion. Then, in

2018, Alnylam announced U.S. Food and Drug Administration (“FDA”) approval for the company’s first commercial product, the medication Patisiran, sold under the brand name “Onpattro.”

5. Onpattro treats a rare and, if untreated, fatal genetic disease known as hereditary transthyretin-mediated amyloidosis or “hATTR” amyloidosis. Onpattro works by delivering siRNA into the patient’s cell, using the composition that Drs. Sood and Lopez-Berestein invented and claimed in the ’717 Patent. Without Drs. Sood’s and Lopez-Berestein’s invention, Onpattro would not exist and hATTR patients would have continued to suffer.

6. Alnylam has benefited handsomely from its unlicensed use of Drs. Sood’s and Lopez-Berestein’s invention. For several years, Onpattro was the only FDA-approved treatment for hATTR amyloidosis and Alnylam’s only commercial product. Patients suffering from hATTR amyloidosis were at risk of death without Onpattro and Alnylam’s revenue from its infringing sales of Onpattro were accordingly large, exceeding \$1.3 billion.

7. Alnylam does not have and has never had a license to the ’717 Patent. By infringing the ’717 Patent, Alnylam has avoided paying MD Anderson license fees that would have otherwise funded the important work of MD Anderson’s clinical physicians and research scientists to fight cancer and save and improve cancer patients’ lives. MD Anderson is entitled to compensation for Alnylam’s infringement.

THE PARTIES AND JOINDER

8. The Board of Regents of the University of Texas System is an agency of the State of Texas, having a location at 210 West 7th Street, Austin, Texas 78701. *See, e.g.*, Tex. Educ. Code Ann. § 65.01, § 65.02, § 65.11, § 65.31. The University of Texas M. D. Anderson Cancer Center is a member institution of The University of Texas System, having a location at 1515 Holcombe Blvd, Houston, Texas 77030. *See, e.g.*, Tex. Educ. Code Ann. § 65.01, § 65.02, § 65.11,

§ 65.31, § 73.101, § 73.103.

9. Defendant Alnylam Pharmaceuticals Inc. (“Parent Alnylam”) is a corporation organized and existing under the laws of Delaware with regular and established places of business in this District.

10. Alnylam U.S., Inc. (“Subsidiary Alnylam”) is a corporation organized and existing under the laws of Delaware with regular and established places of business in this District. Subsidiary Alnylam is a wholly owned subsidiary of Parent Alnylam. Parent Alnylam and Subsidiary Alnylam jointly conduct their activities regarding Onpattro such that Parent Alnylam has named Subsidiary Alnylam as a real party in interest to its litigation involving infringement by Onpattro. *See Alnylam Pharms., Inc. v. Silence Therapeutics GmbH*, PGR2018-00059, Paper 2 at 3 (P.T.A.B. Apr. 2, 2018).

SUBJECT MATTER JURISDICTION

11. This Court has subject matter jurisdiction over the patent infringement claims asserted in this case under 28 U.S.C. §§ 1331 and 1338(a).

PERSONAL JURISDICTION AND VENUE

12. This Court has personal jurisdiction over Alnylam pursuant to Texas’ long-arm statute, Tex. Civ. Prac. & Rem. Code Ann. §§ 17.041-17.045, which extends jurisdiction as far as the federal constitutional requirements of due process will permit.

13. Venue and jurisdiction are appropriate under 28 U.S.C. § 1400.

14. Alnylam has regular and established places of business in this District and commits acts of infringement in this District. For example, Alnylam sales, patient education, medical education and other personnel work in this District and commit acts of infringement, including by using, instructing other to use, marketing, selling, and offering to sell Onpattro, and inducing others to do the same. Ex. 3 (employee LinkedIn pages); Ex. 4 (job postings); Ex. 5 (infusion documents).

Alnylam conducts and controls clinical research in this District, including research relating to and involving the administration of Onpattro. Ex. 6 (clinical research documents).

THE '717 PATENT

15. On November 24, 2016, the U.S. Patent and Trademark Office issued U.S. Patent No. 8,895,717, entitled “Delivery of siRNA by neutral lipid compositions,” listing Anil K. Sood, Gabriel Lopez-Berestein, Charles N. Landen, and Arturo Chavez-Reyes as inventors. A true and correct copy of the '717 Patent is attached hereto as Exhibit 1 and incorporated herein by reference. The '717 Patent claims priority from Provisional Patent Application No. 60/671,641 filed April 15, 2005.

16. By assignments dated October 24 and 31, 2007, each inventor assigned their entire interest in the '717 Patent to Plaintiff who recorded the assignment with the U.S. Patent and Trademark Office on January 15, 2008 at Reel/frame 020367/0201. Accordingly, Plaintiff is the owner of all right, title, and interest in the '717 Patent.

17. Alnylam is not licensed to practice the '717 Patent.

18. The '717 Patent is valid and enforceable.

COUNT I: INFRINGEMENT OF THE '717 PATENT

19. MD Anderson incorporates by reference the forgoing paragraphs.

20. As shown in Exhibit 2, Onpattro literally meets each claim limitation of at least claims 2, 10, and 11 of the '717 Patent. To the extent that Onpattro does not literally meet any claim limitation, it does so under the doctrine of equivalents.

21. Alnylam infringes the '717 Patent under 35 U.S.C. § 271(a) by making Onpattro in the United States.

22. Alnylam infringes the '717 Patent under 35 U.S.C. § 271(a) by selling and offering to sell Onpattro, including to pharmacies, infusion centers, or home infusion administrators, in the

United States. Ex. 5 (infusion centers).

23. Alnylam infringes the '717 Patent under 35 U.S.C. § 271(a) by using Onpattro in its clinical research. Ex. 6 (clinical research).

24. Alnylam infringes the '717 Patent under 35 U.S.C. § 271(b) by marketing Onpattro to doctors, patients, pharmacies, and infusion centers, selling it to them, and instructing them how use and sell Onpattro, including as part of Alnylam's research. Ex. 5 (infusion centers); Ex. 6 (clinical research).

25. Alnylam's infringement is willful. Alnylam was aware of the then-pending patent application that published on January 8, 2009 and later issued as the '717 Patent, at least by virtue of the presentations Drs. Sood and Lopez-Berestein gave to the company and its subsequent interactions with the inventors and MD Anderson.

26. As a result of Alnylam's acts of infringement, MD Anderson has suffered and continues to suffer damages. However, MD Anderson does not yet know the full extent of the infringement and the amount of damages cannot be ascertained except through discovery and special accounting. To the fullest extent permitted by law, MD Anderson seeks recovery of damages at least for reasonable royalties, unjust enrichment, and benefits received by Onpattro as a result of using the patented technology. MD Anderson further seeks any other damages to which it is entitled under law or in equity.

DEMAND FOR JURY TRIAL

27. MD Anderson hereby demands a jury trial for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor as follows:

A. That Judgment be entered that Defendant has infringed one or more claims of the '717

Patent, literally and under the doctrine of equivalents;

- B. An award of damages sufficient to compensate for Defendant's infringement under 35 U.S.C. § 284;
- C. Exemplary damages for willful infringement;
- D. That the case be found exceptional under 35 U.S.C. § 285 and that Plaintiff be awarded its reasonable attorneys' fees;
- E. Costs and expenses in this action;
- F. An award of prejudgment and post-judgment interest; and
- G. Such other and further relief as the Court may deem just and proper.

Dated: December 12, 2024.

McKool Smith, P.C.

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